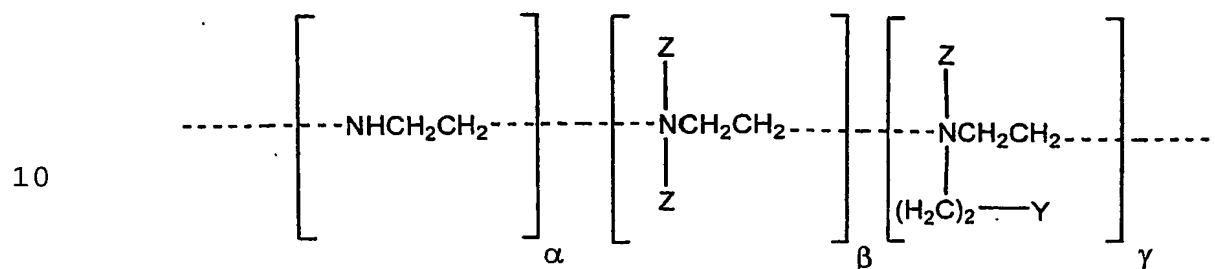


CLAIMS

1. A polyethylenimine polymer according to the following formula:

5



wherein α is between 0 to 90%;

15 β is between 0 to 100%;

γ is between 0 to 50%;

wherein $\alpha + \beta + \gamma = 100\%$; and

the Z groups are hydrophobic and are independently hydrogen or any linear or branched, substituted or unsubstituted, or cyclo form of any hydrophobic substituent; and

Y may represent a hydrophilic substituent.

2. A polyethylenimine polymer according to claim 1 wherein the monomer units identified with α , β and γ form any arrangement in the polyethylenimine polymer.

3. A polyethylenimine polymer according to claim 1 wherein the arrangement of the α , β and γ units are random or in a block copolymer form such as $\alpha\beta\gamma\alpha\beta\gamma$.

4. A polyethylenimine polymer according to any preceding claim wherein the polyethylenimine polymer is linear or branched.

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5. A polyethylenimine polymer according to any preceding claim wherein the Z groups are independently

selected from any of the following hydrophobic substituents: an alkyl, an alkenyl, and alkynyl, an aryl, an acyl, a hydroxy alkyl, a hydroxy acyl, polyethylene glycol or any sugar.

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6. A polyethylenimine polymer according to any preceding claim wherein the Z groups are independently any linear or branched, substituted or unsubstituted, or cyclo form of the following alkyl, alkenyl, alkynyl, aryl, acyl, hydroxy alkyl, hydroxy acyl, polyethylene glycol or any sugar groups: $C_1 - C_{20}$; $C_1 - C_{12}$; $C_1 - C_6$ or C_1 .

10

7. A polyethylenimine polymer according to any of claims 1 to 4 wherein the Z groups are $C_1 - C_4$ linear alkyl groups.

15

8. A polyethylenimine polymer according to any preceding claim wherein Y represents any of the following: $-NH_2$; $-NHA$; $-N^+R_1R_2R_3$; and $-N^+R_1R_2A$.

20

9. A polyethylenimine polymer according to claim 8 wherein R_1 , R_2 , or R_3 is selected from any of the following substituents: an alkyl, an alkenyl, an alkynyl, an aryl, an acyl, a hydroxy alkyl, a hydroxy acyl, polyethylene glycol or any sugar.

25

10. A polyethylenimine polymer according to claim 8 wherein R_1 , R_2 and R_3 are independently any linear or branched, substituted or unsubstituted, or cyclo form of the following alkyl, alkenyl, alkynyl, aryl, acyl, hydroxy alkyl, hydroxy acyl, polyethylene glycol or any sugar groups: $C_1 - C_{20}$; $C_1 - C_{12}$; $C_1 - C_6$ or C_1 .

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11. A polyethylenimine polymer according to claim 8 wherein R_1 , R_2 and R_3 are $C_1 - C_4$ linear alkyl groups.

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12. A polyethylenimine polymer according to claim 8 wherein all of R_1 , R_2 and R_3 are CH_3 .

13. A polyethylenimine polymer according to any preceding claim wherein there is between 1 and a maximum of 3 R substituents on any single nitrogen.
- 5 14. A polyethylenimine polymer according to any of claims 8 to 13 wherein the groups A are selected from any of the following linear or branched, substituted or unsubstituted, or cyclo groups: $C_1 - C_{30}$; $C_8 - C_{24}$; or $C_{12} - C_{16}$.
- 10 15. A polyethylenimine polymer according to any of claims 8 to 13 wherein the groups A may be linear $C_{12} - C_{16}$ alkyl groups.
- 15 16. A polyethylenimine polymer according to any of claims 8 to 13 wherein the A groups are $CH_3(CH_2)_{15}$.
- 20 17. A polyethylenimine polymer according to any preceding claim wherein the ratio of quaternary ammonium nitrogens to nitrogens of amino groups is selected from any of the following: 0.01% - 100%; 10% - 90%; 30% - 70%; 40% - 60%; 50% - 90%; 60% - 80% or 40% - 90%.
- 25 18. A polyethylenimine polymer according to any preceding claim wherein a parent polyethylenimine compound used to make the polyethylenimine polymer has an average molecular weight of about 2 - 50kD, or of about 10 - 25 kD.
- 30 19. A polyethylenimine polymer according to any preceding claim wherein the polyethylenimine polymer has an average molecular weight of about 10 - 25 kD.
- 35 20. A polyethylenimine polymer according to any preceding claim wherein the polyethylenimine polymer produces hydrophobic domains.
21. A polyethylenimine polymer according to claim 20 wherein the level of hydrophobic modification is from

about 0.01 - 50%, about 0.1 - 20% or about 1 - 10% of amino groups.

22. A polyethylenimine polymer according to any preceding claim wherein monomeric subunits in accordance with the structure as defined in formula I shown below:

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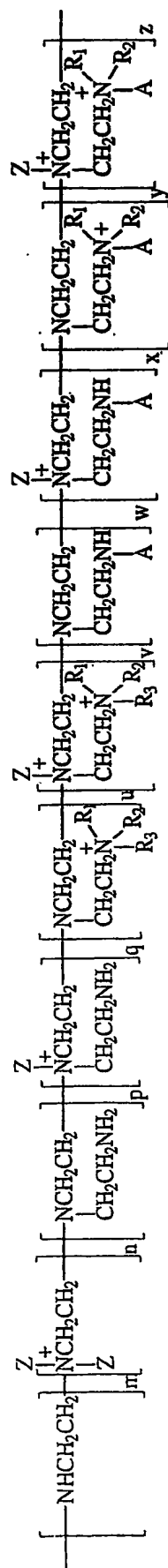
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wherein m is between 0 - 90 %;
n is between 0 - 100 %;
p is between 0 - 50 %;
q is between 0 - 50 %;
5 u is between 0 - 50 %;
v is between 0 - 50 %;
w is between 0 - 20 %;
x is between 0 - 20 %;
y is between 0 - 20 %; and
10 z is between 0 - 20 %;
wherein, $m + n + p + q + u + v + w + x + y + z = 100\%$.

23. A polyethylenimine polymer according to claim 22
15 wherein the monomer units m, n, p, q, u, v, w, x, y and z are arranged in any order.

24. A polyethylenimine polymer according to any preceding claim wherein
20 when $m = 0\%$ then n is not equal to 0%;
when $n = 0\%$ then m is not equal to 0 %;
when $p = 0\%$ then $q + u + v + w + x + y + z$ does not equal 0%;
when $q = 0\%$ then $p + u + v + w + x + y + z$ does not
25 equal 0%.;
when $u = 0\%$ then $p + q + v + w + x + y + z$ does not equal 0%.
when $v = 0\%$ then $p + q + u + w + x + y + z$ does not equal 0%;
30 when $w = 0\%$ then $x + y + z + n$ does not equal 0%;
when $x = 0\%$ then $w + y + z + n$ does not equal 0%;
when $y = 0\%$ then $w + x + z + n$ does not equal 0%;
when $z = 0\%$ then $w + x + y + n$ does not equal zero.

35 25. A polyethylenimine polymer according to any of claims 22 to 24 wherein $m + n$ lies between 50 to 100%.

26. A polyethylenimine polymer according to any of claims 22 to 25 wherein $p + q + u + v$ lies between 20 to 50%.
- 5 27. A polyethylenimine polymer according to any of claims 22 to 26 wherein $w + x + y + z$ lies between 0.01 to 10%.
- 10 28. A polyethylenimine polymer according to any of claims 22 to 27 wherein p, q, u, v, w, x, y or z are equal to 0%.
- 15 29. A polyethylenimine polymer according to any of claims 22 to 27 wherein the sum total of p, q, u, v, w, x, y and z is equal to a value greater than 0% thereby forming a branched compound.
- 20 30. A polyethylenimine polymer according to any of claims 22 to 27 wherein w, x, y or z are equal to 0%.
31. A polyethylenimine polymer according to claim 22 wherein $m + n = 60\%$, $w + x + y + z = 6\%$, and $p + q + u + v = 34\%$.
- 25 32. A method of forming a polyethylenimine polymer according to any of claims 1 to 31 by reacting a polyethylenimine compound formed from the polymerisation of ethylenimine with a first organo halide to form an organo side chain on the polyethylenimine compound, and
- 30 then a second organo halide to react with an amino group on the polyethyleneimine compound.
33. A method according to claim 32 wherein the ethylenimine is branched or linear.
- 35 34. A method according to any of claims 32 and 33 wherein the first organo halide is any linear or branched, substituted or unsubstituted, or cyclo form of

any alkyl, alkenyl, alkynyl, aryl or acyl halide or any hydrophilic halide.

35. A method according to any of claims 32 to 34 wherein
5 the organo group of the first organo halide is selected from any of the following linear or branched, substituted or unsubstituted, or cyclo groups: $C_1 - C_{30}$; $C_8 - C_{24}$; or $C_{12} - C_{16}$.

10 36. A method according to any of claims 32 to 34 wherein the first organo halide is a linear $C_{12} - C_{16}$ alkyl halide.

37. A method according to any of claims 32 and 33 wherein the first organo halide is cetyl bromide (e.g.
15 $CH_3(CH_2)_{15} Br$).

38. A method according to any of claims 32 to 37 wherein the second organo halide is an alkyl, alkenyl, alkynyl, aryl or acyl halide or any hydrophilic halide.

20 39. A method according to any of claims 32 to 38 wherein the organo group of the second organo halide is selected from any of the following linear or branched, substituted or unsubstituted, or cyclo groups: $C_1 - C_{20}$; $C_1 - C_6$; or C_1 .

25 40. A method according to any of claims 32 to 37 wherein the second organo halide is a linear $C_1 - C_6$ alkyl halide.

41. A method according to any of claims 32 to 37 wherein
30 the second organo halide is methyl iodide.

42. A method according to any of claims 32 to 41 wherein the polyethylenimine compound and first organo halide are mixed in an organic solvent such as tetrahydrofuran,
35 which is then refluxed in an alcoholic solution of sodium hydroxide, and cetyl polyethylenimine is then isolated and reacted with the second organo halide.

43. A method according to any of claims 32 to 42 wherein the second organo halide is added in the presence of a metal hydroxide (e.g. sodium hydroxide), a metal halide (e.g. sodium iodide) and an alcohol (e.g. methanol).

5

44. A composition comprising a polyethylenimine polymer according to any of claims 1 to 31 and a pharmaceutically acceptable carrier.

10 45. A composition according to claim 44 wherein the ratio of polyethylenimine polymer to pharmaceutically acceptable carrier ranges from any of the following: 0.0001 - 100 w.v., 0.005 - 50 w.v.; 0.001 - 30 w.v.; 0.001 - 10 w.v.; or 0.01 - 1 w.v.

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46. A pharmaceutical composition comprising a polyethylenimine polymer according to any of claims 1 to 31 and a drug.

20 47. A pharmaceutical composition according to claim 46 wherein the drug is poorly soluble in aqueous solvents such as water.

25 48. A pharmaceutical composition according to any of claims 46 and 47 wherein the drug is selected from any of the following: cyclosporin; steroids such as prednisolone, oestradiol, testosterone; drugs with multicyclic ring structures which lack polar groups such as paclitaxel; and drugs such as etoposide.

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49. A pharmaceutical composition according to any of claims 45 to 48 wherein the ratio of the polyethylenimine polymer to the drug is selected from any of the following: 0.001 - 100%; 0.1 - 100%; 1 - 100%; 10 - 90%;
35 30 - 70%.

50. A pharmaceutical composition according to any of claims 46 to 49 wherein the pharmaceutical composition also comprises a pharmaceutically acceptable carrier.

51. A pharmaceutical composition according to any of claims 46 to 50 wherein the ratio of polyethylenimine polymer to drug to pharmaceutically acceptable carrier
5 may be in the range of about 5 - 20mg : 0.5 - 5mg : 0.5 - 5mL or 5 - 20mg : about 5 - 5mg : 0.5 - 5g; about 10mg:2mg:1mL; or about 10mg:2mg:2g.

52. A pharmaceutical composition according to any of
10 claims 50 and 51 wherein the pharmaceutical composition is in the form of any of the following: tablets, suppositories, liquid capsule powder form, or a form suitable for pulmonary delivery.

15 53. A method of dissolving poorly soluble drugs suitable for oral delivery, using a preformed polymer.

54. A method according to claim 53 wherein the preformed polymer is a polyethylenimine polymer according to any of
20 claims 1 to 31.

55. A method according to any of claims 53 and 54 wherein the poorly soluble drug is selected from any of the following: cyclosporin; steroids such as prednisolone;
25 oestradiol; testosterone; drugs with multicyclic ring structures which lack polar groups such as paclitaxel; drugs such as etoposide.

56. Use of a preformed polymer according to any of
30 claims 1 to 31 in dissolving poorly soluble drugs in the preparation of a composition.

57. Use according to claim 56 wherein the composition is pharmaceutical composition comprising a drug and/or a
35 pharmaceutically acceptable carrier.